CLAIMS

We claim:

1. A composition comprising at least one digitalis glycoside and a cyclodextrin.

2. The composition of claim 1, further defined as a pharmaceutical composition comprising the at least one digitalis glycoside and an amorphous cyclodextrin.

3. The composition of claim 2, wherein the pharmaceutical composition comprises one or more excipients.

4. The composition of claim 2, wherein pharmaceutical composition comprises one or more pharmaceutically acceptable antioxidants.

5. The composition of claim 2, wherein the pharmaceutical composition comprises one or more pharmaceutically acceptable preservatives.

6. The composition of claim 2, wherein the pharmaceutical composition comprises one or more pharmaceutically acceptable buffering agents.

7. The composition of claim 2, wherein the pharmaceutical composition comprises one or more pharmaceutically acceptable polysaccharides.

8. The composition of claim 3, wherein the said excipients comprises mannitol, sorbitol, fructose, glucose, lactose, sucrose, trehalose or any other water soluble sugar.

9. The composition of claim 4, wherein the said antioxidants comprise ascorbic acid, sodium ascorbate, sodium bisulfate, sodium metabisulfate, curcumin, curcumin derivatives, ursolic acid, resveratrol, resveratrol derivatives, alpha-lipoic acid or monothio glycerol.

10. The composition of claim 5, wherein the said preservatives comprise a methylparaben, methylparaben sodium, propylparaben, propylparaben sodium, benzalkonium chloride, or benzthonium chloride.

11. The composition of claim 6, wherein the said buffering agents comprise monobasic and dibasic sodium phosphate, sodium benzoate, potassium benzoate, sodium citrate, sodium acetate or sodium tartrate.

12. The composition of claim 7, wherein the polysaccharides comprise dextran sulfate, pectin, modified pectin, insoluble 1,3- β-D glucan, micronized 1,3- β-D glucan, soluble 1,3- β-D glucan, phosphorylated 1,3- β-D glucan, aminated 1,3- β-D glucan or carboxymethylated 1,3- β-D glucan, sulfated 1,3- β-D glucan.

13. The composition of claim 1 or 2, wherein the digitalis glycoside is oleandrin, neriifolin, odoroside A or H, ouabain (G-strophantin), cymarin, sarmentocymarin, periplocymarin, K-strophantin, thevetin A, cerberin, peruvoside, thevetosin, thevetin B, tanghinin, deacetyltanghinin, echujin, honghelоside G, honghelin, periplocin, strophantidol, nigrescin. uzarin, calotropin, cheiroside A, cheirotoxin, euonoside, euobioside, euomonoside, lancetoxin A and B, kalanchoside, bryotoxin A-C, bryophyllin B, cotiledoside, tyledoside A-D, F and G, orbicuside A-C, alloglaucotoxin, corotoxin, coroglaucin, glaucorin, scillarene A and B, scilliroside, scilliacinoside, scilliglaucoside, scilliglaucosidin, scillirosidin, scillirubrosidin, scillirubroside, proscillaridin A, methyl-proscillaridin A, rubelin, convalloside, convallatoxin, bovoside A, glucobovoside A, bovoruboside, antiarin A, helleborin, hellebrin, adonidin, adonin, adonitoxin, thesiuside, digitoxin, gitoxin, gitalin, digoxin, F-gitonin, digitonin, lanatoside A-C, bufotalin, bufotalinin, bufotalidin, pseudobufotalin, acetyl-digitoxin, acetyl-oleandrin, beta-methyldigoxin or alpha-methyldigoxin.

14. The composition of claim 13 wherein the digitalis glycoside is oleandrin.

15. The composition of claim 13 wherein the digitalis glycoside is odoroside A or odoroside H.

16. The composition of claim 13 wherein the digitalis glycoside is digitoxin.

17. The composition of claim 13 wherein the digitalis glycoside is proscillaridin A.

18. The composition of claim 13 wherein the digitalis glycoside is methyl-proscillaridin A.

19. The composition of claim 13 wherein the digitalis glycoside is neriifolin.

20. The composition of claim 2 wherein said amorphous cyclodextrin has a degree of substitution of 2 to 7.

21. The composition of claim 1 wherein the ratio by weight of digitalis glycoside to amorphous cyclodextrin is 0.01 to 1.

22. A process for preparing a pharmaceutical composition comprising admixing at least one digitalis glycoside with a cyclodextrin and rendering said composition pharmaceutically acceptable.

23. The process of claim 22, wherein the composition is rendered sterile by filtration.

24. The process of claim 22, wherein the composition is freeze-dried or lyophilized.

25. A method of treating a cell proliferative disease in a subject comprising administering an amount of the composition of claim 1 or claim 2 that is effective to treat the cell proliferative disease.

26. The method of claim 25, wherein the subject is a human subject.

27. The method of claim 25, wherein the composition comprises the digitalis glycoside at a concentration of from 0.01 mg per mL to 10 mg per mL.

28. The method of claim 27, wherein the digitalis glycoside is at a concentration of from 0.04 mg per mL to 5 mg per mL.

29. The method of claim 25 wherein the composition is administered to the subject intramuscularly, intravenously or subcutaneously.

30. The method of claim 25, wherein the composition is administered orally, intranasally, rectally or vaginally.